



CAPA for Life Sciences

After receiving training through PathWise, we certainly see a general improvement in our CAPA process, including root cause analysis and documentation.

There is also a reduction in the number of open CAPAs, resulting in less people being involved and less pressure for our organization.

- **Hans Willems**
VP Operations
Boston Scientific

The Life Science industry needs to have trained people they can count on to identify and investigate root causes and effectively implement solutions for corrective and preventive actions. Our CAPA course is designed to effectively develop these individuals and provide them with the skills and tools to become superb investigators and problem solvers.

COURSE OVERVIEW

- **Issue Review** – Identify and prioritize non-conformances based on risk.
- **Root Cause Analysis** – Investigate systemic issues to identify underlying causes.
- **Implementation and Effectiveness Checking** – solution selection, verify and validate, implement, monitor and confirm success.

LEARNING OBJECTIVES

Throughout the course, participants improve their ability to:

- Assess and prioritize each non-conformance based on risk.
- Gather relevant information through specific, focused questioning.
- Pinpoint root causes using facts instead of guesswork or opinion.
- Avoid costly experiments and trial fixes by logically testing possible causes.
- Target potential problems before they happen and develop actions to prevent them.
- Effectively involve others in the investigation process.
- Check effectiveness of corrective / preventive actions.
- Document the analysis in an easy-to-use, logical and defensible format.

AUDIENCE

This course is appropriate for individuals who are regularly called upon to resolve problems, or whose input would aid in preventing problems. Examples include investigators, laboratory, QA/RA functions, managers, manufacturing supervisors, technicians and engineers.

DELIVERY

This course is taught using a blended approach of classroom and real-life application. This “how-to” approach to learning significantly increases knowledge retention, and allows participants to apply the skills they’ve learned in training into a work setting.

The course can be conducted by PathWise facilitators or by certified client instructors. Our facilitators have extensive backgrounds in CAPA and quality system management.